

## REMARKS

Favorable reconsideration and allowance of this application are requested.

### **1. Discussion of Amendments**

Pending independent claim 1 has been further revised to clarify that the core is formed by filaments that show substantially no adhesion to each other. All other claims remain in the form as presented with the prior Amendment dated January 11, 2008.

In addition, pending claim 1 has been further clarified such that the recited yarns include sheath filaments and core filaments with the weight ratio between the sheath and the core filaments being below 5:1. The core filaments thus show substantially no adhesion to each other while the sheath filaments form a substantially non-porous layer around the core filaments. Support for such clarifications can be found at page 3, lines 11-28 and page 4, lines 25-35. *("[T]he polyethylene yarns are sheath and core yarns....In this sheath and core yarn the core is formed by filaments that show no or only little adhesion to each other, that is most filaments can still be separated, e.g. when the yarn is cut lengthwise or the sheath is removed. The sheath of the yarn is a substantially non-porous layer, which layer may for example have been formed from outer filaments of a precursor yarn [being melted] together as a result of heat exposure.")*

Claims 10-15 are new. In this regard, claim 10 is dependent from claim 1 and requires the sheath filaments to be melt-adhered to one another as supported by page 3, lines 16-17 of the specification. Claims 11-14 are directed toward a polyethylene yarn per se having the attributes recited in claim 1. Support for the ratios of sheath filaments to core filaments can be found at page 4, lines 26-27 of the specification. Claim 15 is directed toward a surgical mesh which comprises a yarn of claim 11.

It is suggested that the subject matter of claims 10-15 is properly examined with the subject matter of claims 1-5 in as much as the same attributes of patentability are defined thereby.

Thus, upon entry of this Amendment, amended versions of claims 1-4 and new claims 10-15 will be pending herein for consideration.

## **2. Response to 35 USC §112 Rejection**

The amendment to claim 1 is believed to address the rejection advanced against claims 1-4 under 35 USC §112, second paragraph. Specifically, applicants have changed the original expression objected to by the Examiner to "substantially no adhesion". In this regard, while the term "substantially" is itself a word of degree, applicants note that such words are clearly permitted to be employed in an applicant's claims without running afoul of 35 USC §112 second paragraph.<sup>1</sup> Thus, the clear impact of the phrase "substantially no adhesion" is as stated in the applicants' specification at page 3, lines 13-15 – i.e., that the core filaments show little or no adhesion to one another such that most of the core filaments can still be separated from one another when, for example, the yarn is cut lengthwise or the sheath is removed.

Thus, withdrawal of the rejection advanced under 35 USC §112 is in order.

## **3. Response to 35 USC §103(a) Rejection**

The only remaining issue to be resolved in this application is the Examiner's rejection of prior claims 1-4 as allegedly "obvious" and hence unpatentable over D'Aversa et al (USP 6,090,116) in view of Schmitt et al (USP 6,669,706). As will become evident from the following discussion, neither publication is inappropriate as a reference against the pending claims herein.

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<sup>1</sup> *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002) ("Expression such as 'substantially' are used in patent documents when warranted by the nature of the invention, in order to accommodate minor variations that may be appropriate to secure the invention.")

Applicants note that D'Aversa et al discloses a knitted surgical mesh using monofilament or multifilament polypropylene yarns. D'Aversa et al further discloses that the yarn used to form the mesh may be formed from polyethylene.

Schmitt et al discloses a surgical mesh which can be knitted and is produced from multifilament yarns. In one embodiment, the multifilament yarns are bicomponent yarns composed of a sheath and a core structure.

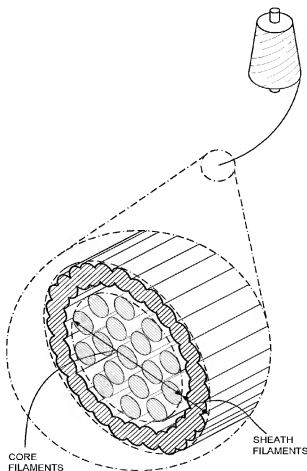
The Examiner alleges that it would have been obvious to the skilled person (35 USC §103(a) to have used the yarns composed of a sheath and core of Schmitt et al in the multifilament of the knitted surgical mesh of D'Aversa et al and thereby arrive at the present invention. The Applicants emphatically disagree for the following reasons.

- (i) **Schmitt et al does not disclose multiple filaments forming a non-porous sheath with other filaments forming a separable core (i.e., filaments that are substantially not adhered to one another and thus can be easily separated)**

It should also be observed that Schmitt et al is directed to **bicomponent** filaments per se. This means that **each** filament 42 of Schmitt includes a core polymer component (noted by reference numeral 46 in Fig. 6 of Schmitt) and a contiguous outer sheath polymer component (noted by reference numeral 44 in Fig. 6 of Schmitt). Such a bicomponent filament is quite different indeed from a yarn which itself is comprised of **multiple filaments** wherein (a) some filaments in the yarn are in a core region and show substantial no adhesion to one another (i.e., filaments that are not adhered to one another and thus can be easily separated), and (b) other filaments in the yarn are in a sheath region with such sheath filaments providing a substantially non-porous layer surrounding the core filaments. The latter attributes are of course those of the presently claimed invention and are nowhere taught or suggested by Schmitt.

A cross-sectional schematic representation of a single yarn end in accordance with the present invention is depicted in Sketch A below. As shown, its construction as

claimed herein is clearly distinguishable from the multiple bicomponent filament yarn of Schmitt et al. Note in this regard that the sheath filaments as schematically depicted in Sketch A form a substantially non-porous layer around the core filaments (e.g., due to the sheath filaments being melt-adhered to one another), while the core filaments show substantially no adhesion to one another (e.g., so they may be separated from one another upon lengthwise sectioning of the yarn or removal of the sheath filaments).



SKETCH A

Thus, while Schmitt et al does in fact acknowledge multifilamentary polyethylene yarns as being part of the prior art (i.e., via USP 3,054,406 and depicted in FIGS. 1 and

1a of Schmitt et al), there is still no disclosure or suggestion therein that such yarns have individual core filaments which show substantially no adhesion to one another and individual sheath filaments which provide a substantially non-porous layer surrounding the core filaments. Indeed, FIG. 1 of Schmitt et al cannot possibly form a "non-porous" sheath of filaments surrounding core filaments thereof.

Schmitt et al actually teaches away from the presently claimed invention. Specifically, as noted above, while Schmitt et al does in fact employ bicomponent filaments having a sheath polymer component and a core polymer component, it is the sheath polymer component which melts and encapsulates the core polymer component according to one embodiment of Schmitt et al as discussed at column 6, lines 15-19 (*"...when the filament is heated to an articular temperature, the sheath will soften and flow together with sheaths from adjacent filaments, thereby filling the void space between filaments and encapsulating the cores of such filaments."*)

Alternatively, Schmitt et al discloses that filaments may be encapsulated by a per-applied resin matrix 30 with the depth of penetration of the matrix 30 being controlled by the quantity of resin applied to the yarn and/or by regulating the coating time. (See column 5, lines 9-37, especially at lines 23-25).

Thus, even if the bicomponent filaments of Schmitt were employed in the mesh of D'Aversa et al, the presently claimed invention would still not be the result. That is, there is no disclosure or suggestion therein of providing a yarn which itself is comprised of **multiple filaments** wherein (a) some filaments in the yarn are in a core region and show substantial no adhesion to one another (i.e., filaments that are not adhered to one another and thus can be easily separated), and (b) other filaments in the yarn are in a sheath region with such sheath filaments providing a substantially non-porous layer surrounding the core filaments.

**(ii) The skilled person is taught away from combining D'Aversa et al with Schmitt et al.**

Schmitt et al notes that USP 3,054,406 discloses a surgical mesh which may be woven from either monofilament or multifilament polyethylene yarns. Schmitt et al states that the surgical mesh woven from monofilament or multifilament polyethylene yarns as described in USP 3,054,406 have a disadvantage. Therefore, it follows that the skilled person is taught by Schmitt et al that the use of polyethylene yarns is disadvantageous. As such, the skilled person is taught away from combining the sheath and core structure of Schmitt et al with the polyethylene yarn forming the knitted surgical mesh of D'Aversa et al.

**(iii) The Combination of Schmitt et al with D'Aversa et al will not result in the presently claimed invention.**

Even if it is assumed for the moment that the ordinarily skilled person would, despite being discouraged to do so, combine the complete teaching of Schmitt et al with D'Aversa et al, such a combination would not result in the present invention.

In this regard, Schmitt et al describes a yarn consisting of a bicomponent monofilament with the first component arranged in sheath and the second component arranged in core. In such a yarn, the sheath is formed of a material having a melting or fusing point lower than that of the material forming the core of the filament (col. 6, lines 12-15). It is thereby taught that different materials should be used for sheath and core of the yarn. This is emphasized in the (single) example where the sheath is a polyethylene terephthalate/isophthalate co-polyester and the core is a polyethylene terephthalate polyester (col. 6, l. 24-26). Therefore, the skilled person combining the teaching of Schmitt et al and D'Aversa et al might obtain either a sheath or a core of polyethylene, but never both of polyethylene.

**(iv) The specific ranges of properties are not disclosed in the publications.**

Furthermore, as the examiner admits, the feature that the yarns are sheath and core yarns having a specific weight ratio between the sheath, namely below 5:1, is not disclosed in either D'Aversa et al or Schmitt et al. This weight ratio has the advantage that flexibility is enhanced, specifically for polyethylene.

Moreover, as the examiner also admits, the tensile strength property and relative viscosity property of the polyethylene specified in claim 1 are not disclosed in D'Aversa et al or Schmitt et al. In the first place, Schmitt et al does not even disclose the use of polyethylene yarns in its own mesh. Polyethylene yarns are disclosed only in the prior art USP 3,054,406 of Schmitt et al which was published more than 50 years ago – i.e., decades before the high performance polyethylene yarns used in the soft tissue mesh of the present invention were developed. The tensile strength property and relative viscosity property of the polyethylene specified in claim 1 could therefore certainly not have been "inherently" disclosed in USP 3,054,406 since high performance polyethylene yarns which yield such properties were decades away from conception.

At least for the above reasons, therefore, the present invention of claim 1 is patentably unobvious over the combination of D'Aversa et al and Schmitt.

Withdrawal of the rejection advanced under 35 USC §103(a) based on D'Aversa et al and Schmitt is therefore in order.

**SNIJDER et al**  
**Serial No. 10/537,895**  
August 13, 2008

**4. Fee Authorization**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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